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TITLE: High-Resolution Speckle-Free Ultrasound Imaging System-A Potential Solution for Detecting Missed Breast Cancer

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13. ABSTRACT ***(Maximum 200 Words)***

The Imperium Inc transmission ultrasound system is a highly promising novel method for imaging the breast. In this pilot project, we are to work with Imperium to advise and help them modify their existing system for non-destructive testing into one suitable for breast imaging, perform a physics evaluation and perform a small clinical pilot feasibility trial. The initiation of this project has been delayed by non-approval of the human use portion of the project. This was submitted twice to the Army with no response. The third submission resulted in a response on August 1, 2001. The Army reviewer asked for revision of the protocol that had been previously approved by the Georgetown Institutional Review Board. These revisions were made and submitted to the Georgetown IRB for approval. The Georgetown IRB has asked for minor modifications and once these are complete and approved the revised protocols will be sent to the Army for approval. During this past year we provided technical advice to Imperium, but have not been able to conduct the detailed tests as planned. I am hopeful that the current requested revisions will be approved by the Georgetown and then the Army review process.

14. SUBJECT TERMS
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Introduction

The Imperium Inc. transmission ultrasound system is a highly promising novel method for imaging the breast. In this pilot project, we are to work with Imperium to advise and help them modify their existing system for non-destructive testing into one suitable for breast imaging, perform a physics evaluation of the system and perform a small clinical pilot feasibility trial. The initiation of this project has been delayed by non-approval of the human use portion of the project. This was submitted twice to the Army with no response. The third submission resulted in a response on August 1, 2001. The Army reviewer asked for revision of the protocol that had been previously approved by the Georgetown Institutional Review Board. These revisions were made and submitted to the Georgetown IRB for approval. The Georgetown IRB has asked for minor modifications and once these are complete and approved, the revised protocols will be sent to the Army for approval. During this past year we provided technical advice to Imperium, but have not been able to conduct the detailed tests as planned. I am hopeful that the current requested revisions will be approved by the Georgetown and then the Army review process.

Body

During the past year we have used only minimal funds because we did not have Army Human Subjects approval. Despite repeat submission of the Human Subjects material, we did not receive a response till August 1, 2001. This has not prevented us from meeting with the company and evaluating the progressive improvements made in the Imperium device. We have visited their factory and have worked with the system at Georgetown to learn how the controls operate and to suggest improvements that should be made prior to rigorous testing. The original system used a water bath. This has been supplemented by a dry system in which fluid filled stand-off pads are used to make contact with the artificial tissue under evaluation. We accompanied the company when they had an informal conference with the FDA. This was done to start their learning process of the requirements for eventual FDA approval. Safety information was extensively discussed and there appear to be no safety concerns.

Key Research Accomplishments

Because we did not have Human Subjects approval to proceed, we were unable to start the project. Based on our advise the company is making improvements in the user interface and the mechanical functioning of the C-arm that supports the device when it is in use.

Reportable Outcomes

None to date

Conclusions

During the delay in initiation of this project, we have seen significant improvement in the design and operating characteristics of the Imperium C-Scan Transmission Ultrasound system. I am hopeful that the Human Subjects re-design requested by the US Army Reviewer will receive approval from Georgetown's IRB within the next 2 months and that Army approval will follow shortly thereafter. I would very much like to officially start this most important project.

References: None

Appendices: None.